K132802

SHANGHAI MOTEX HEALTHCARE CO., LTD.
No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
Telephone: 86-21-5979 9888 Fax: 86-21-23010718

MAY 2 1 2014

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **Shanghai Motex Healthcare Co., Ltd.**
- Address: No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
- Owner Number: **9041164**
  Registration Number: **9615978**
- Contact Person: Dr. Jen, Ke-Min
  E-mail: ceirs.jen@msa.hinet.net Tel: +886-3-5208829 ; Fax: +886-3-5209783
- Date Prepared: May 20, 2014

Device

- **Proprietary Name:** Motex Powdered Nitrile Surgical Gloves, Item 6010 White
  Motex Powdered Nitrile Surgical Gloves, Item 6010 Green
- **Common Name:** Surgeon's glove
- **Classification Name:** Surgeon's Gloves
- **Product Code:** KGO
- **Regulation Number**: Class I, 878.4460

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to NUZONE Nitrile Powdered Surgical Gloves (K000178)
- **Device Description:**
  Motex Powdered Nitrile Surgical Gloves are made of synthetic rubber. They are sterilized by radiation, and intended to be used in surgery to prevent the cross contamination between patient and user.
- **Indications for Use:**
  The Motex Powdered Nitrile Surgical Gloves are sterile disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
- **Device Characteristics:**
  Single use only. Not made with natural rubber latex.

- **Technological Characteristics:**

Motex Powdered Nitrile Surgical Gloves characteristics are summarized below compared to ASTM and ISO standards to the predicate device:

Characteristic	Standard
Dimensions	ASTM D3577-09e1
Physical Properties	ASTM D3577-09e1
Freedom from Holes	ASTM D3577-09e1
Water leak testing	ASTM D5151-06
Residual powder testing	ASTM D6124-06
Water extractable protein testing	ASTM D5712-10
Biocompatibility	ISO 10993-10:2010
	ISO 10993-12:2007
Sterilization Validation	ISO 11137-1:2006
	ISO 11137-2:2006

- **Powder Residual:**

Surgeon's gloves meet powder level requirements for "Powder" designation per ASTM D6124-06, Standard test method for residual powder on medical gloves. The results generated values will below 15mg/dm^2 of residual powder per glove.

- **Biocompatibility Test Reports:**

According to ISO 10993 series standards, we completed the biological evaluation and the results of these studies show that the Motex Powdered Nitrile Surgical Gloves safe for their intended use. Besides, we also completed the following reports for each item 6010_White and 6010_Green including:

- Skin Sensitization Test (Maximization test), Sesame oil extract;
- Skin Sensitization Test (Maximization test), Sodium Chloride extract;
- Skin Irritation Test, Sesame oil extract;
- Skin Irritation Test, Sodium Chloride extract;

- **Clinical Data:**

Not applicable.

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Comparison Table

Similarity:

Comparison Feature	Predicate device	Subject device
Device name	Nuzone Nitrile Surgical Gloves, Powdered, Green **(K000178)**	Motex Powdered Nitrile Surgical Gloves **(K132802)**
Indications For Use	The surgical glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	The Motex Powdered Nitrile Surgical Gloves are sterile disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
Prescription/OTC Device	Over-the-Counter Use	Over-the-Counter Use
Product code	KGO, Class I, 878.4460	KGO, Class I, 878.4460
Device Design	They are coated with nitrile coating and are offered powdered and sterile.	They are coated with nitrile coating and are offered powdered and sterile.
Major Material Composition	Nitrile and Absorbable dusting powder	Nitrile: Acrylonitrile- butadiene rubber latex; i.e. NBR (CAS# 9003-18-3) Absorbable dusting powder USP (FDA PMA Number: P890070)
Performance Test for Pinhole, Dimensions, and Physical properties	Meets ASTM D3577-09	Meets ASTM D3577-09
Biocompatibility	Primary Skin irritation test ASTM F 719-81 and Dermal Sensitization Test ASTM F720-81, indicates "under the conditions of the study, not an irritant" and "under conditions of the study, not a sensitizer."	Meets ISO 10993-10:2010/ ISO 10993-12:2007 Gloves are "under the conditions of the study, not an irritant" and "under conditions of the study, not a sensitizer."
Sterilization Validation	Sterile Nitrile Powdered Surgical Gloves	Meets ISO 11137-1:2006, ISO 11137-2:2006

Powder Residual	N/A	Meets ASTM D6124-06 Results generated values below 15mg/dm^2 of residual powder per glove
Water Extractable Protein Testing	N/A	Meets ASTM D5712-10

Difference:

Product Trade Name	Nuzone Nitrile Surgical Gloves, Powdered, Green	Motex Powdered Nitrile Surgical Gloves 6010_White and 6010_Green
Specification size	N/A	6, 6.5, 7, 7.5, 8, 8.5

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to NUZONE Nitrile Powdered Surgical Gloves (K000178). Both of the subject device and predicate device are the same Powdered Surgical Gloves which have the similar indications for use, material composition with Nitrile, meet the performance tests by ASTM D3577-09, and also completed the biocompatibility, sterilization validation test reports. The major differences of the two devices are the different colorants and specification. That just means the subject devices have two colorants: white and green, and the predicate device has only one green colorant; and the specifications of the subject device are limited on the 6~8.5 sizes. These differences are not relating to the safety or effectiveness aspects. Thus they are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Shanghai Motex Healthcare Company, Limited
C/O Dr. Ke-Min Jen
Official Correspondent
No. 369, Jiasong Zhong Road
Huaxin, Qingpu, Shanghai
CHINA 201708

Re: K132802
Trade/Device Name: Motex Powdered Nitrile Surgical Gloves, Item 6010 White
Motex Powdered Nitrile Surgical Gloves, Item 6010 Green
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 19, 2014
Received: April 24, 2014

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132802

Device Name
Motex Powdered Nitrile Surgical Gloves, Item 6010 White
Motex Powdered Nitrile Surgical Gloves, Item 6010 Green

Indications for Use *(Describe)*
The Motex Powdered Nitrile Surgical Gloves are sterile disposable devices made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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